ATTACHMENT 2

EVALUATION OF RISK OF INADEQUATE PERFORMANCE/FLOWCHART 2

High Risk SUD: Endoscopic Vessel Harvesting Devices (878.4400 GEI)

Question 1: Does postmarket information suggest there is an increased risk of injury when compared to the use of a single use device that has not been reprocessed?

The Company is aware of one adverse event involving an endoscopic vessel harvesting device that was caused by reprocessing that resulted in a deterioration of the mechanical properties of the device. In that instance, a piece of the tubing material that covers the hinge portion of the vein harvester's scissors became brittle after resterilization and broke off into the patient's leg during the harvesting procedure. Open surgery was required to remove the debris from the patient.

The answer to Question 1 is "Yes."

Go to Question 2.

Question 2: Could failure of the device cause death, serious injury, or permanent impairment?

Failure of an endoscopic vessel harvesting device could cause death, serious injury, or permanent impairment.

The answer to Question 2 is "Yes."

Go to Question 3.

Question 3: Do endoscopic vessel harvesting devices contain any materials, coatings, or components that may be damaged or altered by a single use or by reprocessing and/or resterilization/disinfection in such a way that the performance of the device may be adversely affected?

Endoscopic vessel harvesting devices do contain materials, coatings, or components that may be damaged or altered by reprocessing in

such a way that performance of the device may be adversely affected. In addition, multiple use and/or reprocessing of these devices could potentially reduce the functionality of the cutting devices. For example, the force required to activate the bipolar scissors increases greatly after a set number of cycles, and may not be suitable for reuse.

The answer to Question 3 is "Yes."

Go to Question 4.

Question 4: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

There are no such standards, tests, or CDRH guidance documents.

The answer to Question 4 is "No."

Go to Question 5.

Question 5: Can visual inspection determine if performance has been affected?

Critical failure of endoscopic vessel harvesting devices is not always visual or self-evident. For example, a weakening of the adhesive bond strengths throughout the device may not be visible prior to reuse. Likewise, a reduction in the component integrity and electrical insulation may not be obvious until actual use of the reprocessed device on a patient.

The answer to Question 5 is "No."

Thus, endoscopic vessel harvesting devices pose a high risk of inadequate performance if reprocessed and reused.